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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,962	09/08/2003	Mendy S. MacCabee	49321-102	3139
<div>22504 7590 07/03/2007 DAVIS WRIGHT TREMAINE, LLP 1201 Third Avenue, Suite 2200 SEATTLE, WA 98101-3045</div>				
			EXAMINER KIM, JENNIFER M	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 07/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/658,962	Applicant(s) MACCABEE ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 9,10 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-21, 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/5/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' election without traverse of Group I, claims drawn to 1-8, 11-21 and 23, is acknowledged. Accordingly, claims 9, 10 and 22 are withdrawn from consideration since they are non-elected invention.

Claim objection

Claim 1 is objected to because of the following informalities: On line 3, the phrase "ciliated e epithelial" appears to be "ciliated epithelial". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 11, 12, 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "in part" in claims 1 and 11 render the claims indefinite because it is unclear just how much achievement or recovery of the damaged ciliated epithelial structures would qualify the phrase "in part". The phrase is subjective. Therefore, one

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of ordinary skill in the art would not be able to ascertain the degree of treatment "in part".

The remaining claims 2-8 and 12, 21 depend from claims 1 and 11 are indefinite to the extent that they depend on claims 1 and 11.

Claims 13-20 and 23 provide for the **use**, topically, of vitamin A, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13-20 and 23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4, 6-8, 11-12 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Biesalski (U.S. Patent No. 5,556,611) of record.

Biesalski teaches a pharmaceutical preparation consisting of retinoic acid as an active substance suitable for a topical treatment of mucosal disease in man and animal. (abstract). Biesalski teaches the preparation can be formulated in an aerosol formulation. (abstract). Biesalski teaches the effective amount of the active substance is from 0.01-50% by weight. (column 6, line 44). This range encompasses and touches Applicants' amounts set forth in claim 8. Biesalski teaches that the preparation is effective for treating functional impairments in the mucous membranes of humans and animals, in particular in the respiratory epithelium and the epithelia of the nose-throat cavity. Biesalski teaches that the treatment is also useful in reduced activity of the ciliated epithelium and disturbances of the mucous membranes of the reparatory tract. (column 10, lines 24-45). Biesalski teaches the preparation is effective for treating acute and chronic bronchitis, acute and chronic functional disturbances due to impairment of tracheobronchial epithelium and bronchopulmonary dysplasia.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Biesalski (U.S. Patent No. 5,556,611) of record.

Biesalski teaches a pharmaceutical preparation consisting of retinoic acid as an active substance suitable for a topical treatment of mucosal disease in man and animal. (abstract). Biesalski teaches the preparation can be formulated in an aerosol formulation. (abstract). Biesalski teaches the effective amount of the active substance is from 0.01-50% by weight. (column 6, line 44). This range encompasses and touches Applicants' amounts set forth in claim 8. Biesalski teaches that the preparation is

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effective for treating functional impairments in the mucous membranes of humans and animals, in particular in the respiratory epithelium and the epithelia of the nose-throat cavity. Biesalski teaches that the treatment is also useful in reduced activity of the ciliated epithelium and disturbances of the mucous membranes of the reparatory tract. (column 10, lines 24-45). Biesalski teaches the preparation is effective for treating acute and chronic bronchitis, acute and chronic functional disturbances due to impairment of tracheobronchial epithelium and bronchopulmonary dysplasia.

Biesalski do not expressly teach that the surgical intervention is the cause of the damaged ciliated epithelial structure.

It would have been obvious to one of ordinary skill in the art to employ retinoic acid preparation taught by Biesalski for the treatment of damaged ciliated epithelial structure regardless of cause because Biesalski et al. teach that the retinoic acid preparation is effective for the treatment of impaired ciliated epithelium. One would have been motivated to employ the retinoic acid preparation taught by Biesalski for a condition of damaged ciliated epithelium in order to treat the condition or the symptoms of damaged ciliated epithelium at any cause including the damage from the surgical intervention. There is a reasonable expectation of successfully treating damaged ciliated epithelium because Biesalski teaches the effectiveness of the preparation in repairing and treating damaged ciliated epithelium in man or animal.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

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None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Jennifer Kim
Patent Examiner
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Jmk

June 25, 2007